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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------|----------------|----------------------|-------------------------|------------------|--|
| 09/087,871 | 06/02/1998 | GERALD WAGNER | 0708-4038 | 1082 | |
| 7. | 590 12/05/2001 | | | | |
| MORGAN & FINNEGAN | | | EXAMINER | | |
| 345 PARK AV NEW YORK, I | | | GABEL, GAILENE | | |
| | | • | ART UNIT | PAPER NUMBER | |
| | | | 1641 | | |
| | | | DATE MAILED: 12/05/2001 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|--|--|---|----------|--|--|--|
| Office Action Summary | | 09/087,871 | WAGNER, GERALD | | | | |
| | | Examiner | Art Unit | | | | |
| | | Gailene R. Gabel | 1641 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet wi | th the correspondence address | ; | | | |
| A SH THE I - Exter after - If the - If NO - Failu - Any r | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply or period for reply is specified above, the maximum statutory period or to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a re within the statutory minimum of thirt will apply and will expire SIX (6) MON cause the application to become AB | oply be timely filed y (30) days will be considered timely. THS from the mailing date of this communionable ANDONED (35 U.S.C. § 133). | ication. | | | |
| 1)⊠ | Responsive to communication(s) filed on 17.5 | September 2001 . | | | | | |
| 2a)⊠ | This action is FINAL . 2b) Th | is action is non-final. | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | ion of Claims | | | | | | |
| 4)⊠ | Claim(s) 1-21 is/are pending in the application | l. | | | | | |
| | 4a) Of the above claim(s) 13-21 is/are withdraw | vn from consideration. | | | | | |
| 5) 🗌 | Claim(s) is/are allowed. | | | | | | |
| 6)⊠ | Claim(s) 1-12 is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | |
| 8)⊠ | Claim(s) 1-21 are subject to restriction and/or | election requirement. | | | | | |
| Applicat | ion Papers | | | | | | |
| 9)[| The specification is objected to by the Examine | r. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to th | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) | The oath or declaration is objected to by the Ex | aminer. | | | | | |
| - | under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) | Acknowledgment is made of a claim for foreign | n priority under 35 U.S.C. | § 119(a)-(d) or (f). | | | | |
| a) | ☐ All b)☐ Some * c)☐ None of: | | | | | | |
| | 1. Certified copies of the priority document | | | | | | |
| | 2. Certified copies of the priority document | | | | | | |
| * (| 3. Copies of the certified copies of the prio application from the International Bu See the attached detailed Office action for a list | reau (PCT Rule 17.2(a)). | | е | | | |
| 14) 🗌 A | 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachmen | | • | | | | | |
| 1) Notic | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 5) Notice of | Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152 | | | | |
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DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 9/17/01 in Paper No. 14 is acknowledged and has been entered. Claims 6-11 have been amended. Claims 1-21 are pending. Claims 1-12 are under examination.

Restriction Requirement

2. Applicant's traversal of the restriction requirement in Paper No. 14 is acknowledged. The traversal is on the grounds that the inventions are obvious over each other within the meaning of 35 USC § 103.

Applicant's argument is not found persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention so as to warrant separate classification and search. For example, it is technically obvious to perform a method using a specified apparatus or system; however, each of the method and apparatus/system is distinct and independent since the structural requirements of each one as an invention are different. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made FINAL.

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R j ctions Withdrawn

Claim Rejections - 35 USC § 112

- 3. In light of Applicant's amendment and arguments, the rejection of claims 6-12 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.
- 4. In light of Applicant's argument, the rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of Furlong et al. (Clinical Chemistry, 1990), for reason of record.

To reiterate, Lillig discloses a system combining analyzers, each adapted for independent operation and each possessing different operational characteristics for different applications wherein each modular analyzer is adapted to operate as a portion of a system of modular analyzers (see column 2, lines and 8-26 and Figure 3). The system includes a first analyzer and a second analyzer each including a sample

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carousel, analyzing means, and automated probe means for transferring samples from the sampling carousels to the analyzing means. Electronic and electrical interfaces form public and/or private networks between analyzers so as to form the system and operational information and instructions are coded into the analyzers through a disk drive (see column 6, lines 51-65).

Groth teaches computer based neural networks design incorporated into analyzers where measured patient results (analyte concentrations, enzymatic activities, etc.) are compared and referenced with biochemical marker standards from preclassified example cases to provide an indication of a pathology. Groth discloses that the computer system is designed to perform specific computational tasks to support a decision tree that provides a feedback mechanism of what subsequent measurements are to be performed based on the most recent measure; the end product of which provides a diagnostic indication of a pathology (see column 5 and column 8).

Furlong teaches computerized neural network analysis specifically of cardiac data for use as clinical decision-making aid wherein computer hardware and software emulate biological nervous systems formed by interconnected artificial neurons (see page 135, column 1, first full paragraph). Such artificial intelligence programs use algorithmic process for decision making wherein clinicians knowledge has been distilled in a hierarchy of facts or rules wherein the matrix of synaptic weighting factors are calculated using back propagation, supervised learning algorithm (see page 134, column 2, last paragraph).

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One of ordinary skill in the art at the time of the invention would have been motivated to increase automated diagnostic versatility into the high-throughput capacity of modular designed analyzer systems taught by Lillig by incorporating decision support systems such as the computerized neural network as taught by Groth and Furlong because in assessing proper emergency management of crisis patients, especially those suspected of myocardial infarction, specific and accurate results obtained at a limited amount of time coupled with anticipatory diagnostic procedure, are critical to the treatment and survival of patients.

Response to Arguments

- Applicant's arguments filed 9/17/01 have been fully considered but they are not 6. persuasive.
- A) Applicant argues that Lillig, Groth, and Furlong in combination fails to provide Applicant's invention as a whole and there is no motivation or suggestion for modifying the combination to arrive at the claimed invention. Specifically, Applicant contends that neural network taught by both Groth and Furlong is a stark contrast to the reflex algorithm claimed by Applicant because neural network classifies according to predetermined set of biochemical markers and measurements which are fed into a trained neural network, which is diametric to a reflex algorithm wherein determination of a pathology is associated with different possible measurements.

In response, the determination of pathology associated with different possible measurements in "reflex algorithm" is necessarily dependent upon predetermined set of

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biochemical measurements programmed into software for use by the algorithm, in addition to other different possible measurements, to effect a decision tree such as in a neural network design which provides for feedback mechanism including a suggestion to perform other activity or to activate another network structure which Groth refers to as a "feedback connection from conclusive diagnostic unit" (see column 16, lines 42-67) so that further testing, if desired, can be activated into preprogrammed analytical computer software to further analyze a sample. Alternatively, Applicant, by way of admission at page 2 of the specification, discloses that reflex algorithm has been employed in the areas of clinical chemistry and laboratory medicine for the past decade. Therefore, absent evidence to the contrary, the neural network system disclosed by both Groth and Furlong can, otherwise, be designed and programmed to allow reflex algorithm capability such as claimed in the instant invention.

- 7. No claims are allowed.
- 8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel Patent Examiner

3- Salel

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

12/03/0K